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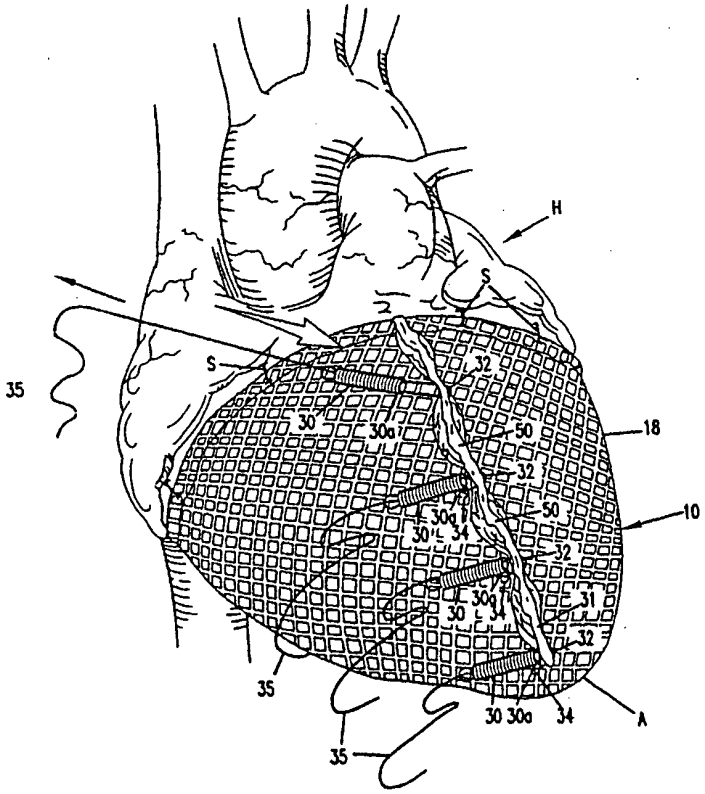
(54) Title: CARDIAC CONSTRAINT WITH DRAW STRING TENSIONING



(57) Abstract: A method and apparatus for treating congestive heart disease and related cardiac complications such as valvular disorders includes a constraining device placed on the heart. The constraining device is a jacket of flexible material of knit construction defining a volume between an open upper end and a lower end. The jacket is dimensioned for the apex of the heart to be inserted into the volume through the open upper end and for the jacket to be slipped over the heart. The jacket is further dimensioned for the jacket to have a longitudinal dimension between the upper and lower ends sufficient for said jacket to constrain said lower portion of the heart. The jacket adapted to be adjusted on the heart to snugly conforming to an external geometry of the heart to constrain circumferential expansion of the heart beyond. A flexible drawstring is laced through the jacket material for the knit material to be bunched together as one end of the drawstring is pulled. A releasable stay member is provided for holding the draw string in a fixed position relative to said jacket upon release of a pulling tension on the draw string with the stay member releasable in response to a resumed pulling tension on the draw string.

CARDIAC CONSTRAINT WITH DRAW STRING TENSIONING

I.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention pertains to a method and apparatus for treating congestive heart disease and related valvular dysfunction. More particularly, the present invention is directed to a cardiac constraint having a releasable tensioning member to tension the constraint on a heart.

2. Description of the Prior Art

Congestive heart disease is a progressive and debilitating illness. The disease is characterized by a progressive enlargement of the heart.

As the heart enlarges, the heart is performing an increasing amount of work in order to pump blood each heart beat. In time, the heart becomes so enlarged the heart cannot adequately supply blood. An afflicted patient is fatigued, unable to perform even simple exerting tasks and experiences pain and discomfort. Further, as the heart enlarges, the internal heart valves may not adequately close. This impairs the function of the valves and further reduces the heart's ability to supply blood.

Causes of congestive heart disease are not fully known. In certain instances, congestive heart disease may result from viral infections. In such cases, the heart may enlarge to such an extent that the adverse consequences of heart enlargement continue after the viral infection has passed and the disease continues its progressively debilitating course.

Patients suffering from congestive heart disease are commonly grouped into four classes (i.e., Classes I, II, III and IV). In the early stages (e.g., Classes I and II), drug therapy is the most commonly prescribed treatment. Drug therapy treats the symptoms of the disease and may slow the progression of the disease. Importantly, there is no cure for congestive heart disease. Even with drug therapy, the disease will progress. Further, the drugs may have adverse side effects.

Presently, the only permanent treatment for congestive heart disease is heart transplant. To qualify, a patient must be in the later stage of the disease (e.g., Classes III and IV with Class IV patients given priority for transplant). Such patients are extremely sick individuals. Class III patients have marked physical activity limitations and Class IV patients are symptomatic even at rest.

drastically slow the progressive nature of congestive heart disease. Unfortunately, currently developed options are experimental, costly and problematic.

Cardiomyoplasty is a recently developed treatment for earlier stage congestive heart disease (e.g., as early as Class III dilated cardiomyopathy). In this procedure, the latissimus dorsi muscle (taken from the patient's shoulder) is wrapped around the heart and chronically paced synchronously with ventricular systole. Pacing of the muscle results in muscle contraction to assist the contraction of the heart during systole.

Even though cardiomyoplasty has demonstrated symptomatic improvement, studies suggest the procedure only minimally improves cardiac performance. The procedure is highly invasive requiring harvesting a patient's muscle and an open chest approach (i.e., sternotomy) to access the heart. Furthermore, the procedure is expensive — especially those using a paced muscle. Such procedures require costly pacemakers. The cardiomyoplasty procedure is complicated. For example, it is difficult to adequately wrap the muscle around the heart with a satisfactory fit. Also, if adequate blood flow is not maintained to the wrapped muscle, the muscle may necrose. The muscle may stretch after wrapping reducing its constraining benefits and is generally not susceptible to post-operative adjustment. Finally, the muscle may fibrose and adhere to the heart causing undesirable constraint on the contraction of the heart during systole.

While cardiomyoplasty has resulted in symptomatic improvement, the nature of the improvement is not understood. For example, one study has suggested the benefits of cardiomyoplasty are derived less from active systolic assist than from remodeling, perhaps because of an external elastic constraint. The study suggests an elastic constraint (i.e., a non-stimulated muscle wrap or an artificial elastic sock placed around the heart) could provide similar benefits. Kass et al., *Reverse Remodeling From Cardiomyoplasty In Human Heart Failure: External Constraint Versus Active Assist*, 91 Circulation 2314 – 2318 (1995). Similarly, cardiac binding is described in Oh et al., *The Effects of Prosthetic Cardiac Binding and Adynamic Cardiomyoplasty in a Model of Dilated Cardiomyopathy*, 116 J. Thorac. Cardiovasc. Surg. 148 – 153 (1998), Vaynblat et al., *Cardiac Binding in Experimental Heart Failure*, 64 Ann. Thorac. Surg. 81 – 85 (1997) and Capouya et al., *Girdling Effect of Nonstimulated Cardiomyoplasty on Left Ventricular Function*, 56 Ann. Thorac. Surg. 867 – 871 (1993).

lower ends sufficient for the jacket to constrain the lower portion of the heart. The jacket is adapted to be adjusted on the heart to snugly conform to an external geometry of the heart. A flexible drawstring is laced through the jacket material for the knit material to be bunched together as one end of the drawstring is pulled. A releasable stay member is provided for holding the draw string in a fixed position relative to the jacket upon release of a pulling tension on the draw string with the stay member releasable in response to a resumed pulling tension on the draw string.

III.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic cross–sectional view of a normal, healthy human heart shown during systole;

Fig. 1A is the view of Fig. 1 showing the heart during diastole;

Fig. 2 is a schematic cross–sectional view of a diseased human heart shown during systole;

Fig. 2A is the view of Fig. 2 showing the heart during diastole;

Fig. 3 is a perspective view of one embodiment of a cardiac constraint device;

Fig. 3A is a side elevation view of a diseased heart in diastole with the device of Fig. 3 in place;

Fig. 4 is a perspective view of an alternative cardiac constraint device;

Fig. 4A is a side elevation view of a diseased heart in diastole with the device of Fig. 4 in place;

Fig. 5 is a cross–sectional view of the device of Fig. 3 overlying a myocardium and with the material of the device gathered for a snug fit;

Fig. 6 is a view similar to Fig. 3A with the device including a releasable tensioning member and before application of tension on the tensioning member; and

Fig. 7 is the view of Fig. 6 following application of tension on the tensioning member.

IV.

DESCRIPTION OF THE PREFERRED EMBODIMENT

A. Congestive Heart Disease

To facilitate a better understanding of the present invention, description will first be made of a cardiac constraint device such as is more fully described in commonly assigned and copending U.S. patent application Ser. No. 09/114,757 filed July 13, 1998. In the drawings, similar elements are labeled similarly throughout.

heart assumes a shape including a generally conical lower portion LP'. During diastole (Fig. 1A), the heart H' is expanding and the conical shape of the lower portion LP' bulges radically outwardly (relative to axis AA'– BB').

The motion of the heart H' and the variation in the shape of the heart H' during contraction and expansion is complex. The amount of motion varies considerably throughout the heart H'. The motion includes a component which is parallel to the axis AA'– BB' (conveniently referred to as longitudinal expansion or contraction). The motion also includes a component perpendicular to the axis AA'–BB' (conveniently referred to as circumferential expansion or contraction).

Having described a healthy heart H' during systole (Fig. 1) and diastole (Fig. 1A), comparison can now be made with a heart deformed by congestive heart disease. Such a heart H is shown in systole in Fig. 2 and in diastole in Fig. 2A. All elements of diseased heart H are labeled identically with similar elements of healthy heart H' except only for the omission of the apostrophe in order to distinguish diseased heart H from healthy heart H'.

Comparing, Figs. 1 and 2 (showing hearts H' and H during systole), the lower portion LP of the diseased heart H has lost the tapered conical shape of the lower portion LP' of the healthy heart H'. Instead, the lower portion LP of the diseased heart H dilates outwardly between the apex A and the A–V groove AVG. So deformed, the diseased heart H during systole (Fig. 2) resembles the healthy heart H' during diastole (Fig. 1A). During diastole (Fig. 2A), the deformation is even more extreme.

As a diseased heart H enlarges from the representation of Figs. 1 and 1A to that of Figs. 2 and 2A, the heart H becomes a progressively inefficient pump. Therefore, the heart H requires more energy to pump the same amount of blood. Continued progression of the disease results in the heart H being unable to supply adequate blood to the patient's body and the patient becomes symptomatic of cardiac insufficiency.

For ease of illustration, the progression of congestive heart disease has been illustrated and described with reference to a progressive dilation of the lower portion LP of the heart H. While such enlargement of the lower portion LP is most common and troublesome, enlargement of the upper portion UP may also occur.

In addition to cardiac insufficiency, the enlargement of the heart H can lead to valvular disorders. As the circumference of the valvular annulus VA increases, the leaflets of the valves TV and MV may spread apart. After a certain amount of

A–V groove AVG and further extends to the lower portion LP to constrain at least the lower ventricular extremities LE.

When the parietal pericardium is opened, the lower portion LP is free of obstructions for applying the jacket 10 over the apex A. If, however, the parietal pericardium is intact, the diaphragmatic attachment to the parietal pericardium inhibits application of the jacket over the apex A of the heart. In this situation, the jacket can be opened along a line extending from the upper end 12' to the lower end 14' of jacket 10'. The jacket can then be applied around the pericardial surface of the heart and the opposing edges of the opened line secured together after placed on the heart. Systems for securing the opposing edges are disclosed in, for example, U.S. Patent No. 5,702,343, the entire disclosure of which is incorporated herein by reference. The lower end 14' can then be secured to the diaphragm or associated tissues using, for example, sutures, staples, etc.

In the embodiment of Figs. 3 and 3A, the lower end 14 is closed and the length L is sized for the apex A of the heart H to be received within the lower end 14 when the upper end 12 is placed at the A–V groove AVG. In the embodiment of Figs. 4 and 4A, the lower end 14' is open and the length L' is sized for the apex A of the heart H to protrude beyond the lower end 14' when the upper end 12' is placed at the A–V groove AVG. The length L' is sized so that the lower end 14' extends beyond the lower ventricular extremities LE such that in both of jackets 10, 10', the myocardium MYO surrounding the ventricles RV, LV is in direct opposition to material of the jacket 10, 10' during diastole. Such placement is desirable for the jacket 10, 10' to present a constraint against dilation of the ventricular portions of the heart H.

After the jacket 10 is positioned on the heart H as described above, the jacket 10 is secured to the heart. Preferably, the jacket 10 is secured to the heart H using sutures (or other fastening means such as staples). The jacket 10 is sutured to the heart H at suture locations S circumferentially spaced along the upper end 12. While a surgeon may elect to add additional suture locations to prevent shifting of the jacket 10 after placement, the number of such locations S is preferably limited so that the jacket 10 does not restrict contraction of the heart H during systole.

While the jacket 10 is expandable due to its knit pattern, the fibers 20 of the knit fabric 18 are preferably non–expandable. While all materials expand to at least a small amount, the individual fibers 20 do not substantially stretch in response to force. In response to the low pressures in the heart H during diastole, the fibers 20

To permit the jacket 10 to be easily placed on the heart H, the volume and shape of the jacket 10 are larger than the lower portion LP during diastole. So sized, the jacket 10 may be easily slipped around the heart H. Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For example, excess material of the jacket 10 can be gathered and sutured S" (Fig. 5) to reduce the volume 16 of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole. Such shape represents a maximum adjusted volume. The jacket 10 constrains enlargement of the heart H beyond the maximum adjusted volume while preventing restricted contraction of the heart H during systole. As an alternative to gathering of Fig. 5, the jacket 10 can be provided with other arrangements for adjusting volume. For example, as disclosed in U.S. Patent No. 5,702,343, the jacket can be provided with a slot. The edges of the slot can be drawn together to reduce the volume of the jacket.

The jacket 10 is adjusted to a snug fit on the heart H during diastole. Care is taken to avoid tightening the jacket 10 too much such that cardiac function is impaired. During diastole, the left ventricle LV fills with blood. If the jacket 10 is too tight, the left ventricle LV cannot adequately expand and left ventricular pressure will rise. During the fitting of the jacket 10, the surgeon can monitor left ventricular pressure. For example, a well-known technique for monitoring so-called pulmonary wedge pressure uses a catheter placed in the pulmonary artery. The wedge pressure provides an indication of filling pressure in the left atrium LA and left ventricle LV. While minor increases in pressure (e.g., 2 – 3 mm Hg) can be tolerated, the jacket 10 is snugly fit on the heart H but not so tight as to cause a significant increase in left ventricular pressure during diastole.

To facilitate a surgeon's ease of use, the present invention provides a releasable tensioning mechanism. In the embodiment shown, the tensioning member includes a spring 30 and associated length of suture 32 to act as a drawstring. The spring 30 may be stainless steel or other biocompatible material. The suture 32 may be commercially available suture material such as polyester or polypropylene. In Fig. 6, a seam 31 is shown formed in the material of the jacket 10 as part of the process of shaping flat sheet material into the shape of the jacket 10. The seam 31 extends generally parallel to the longitudinal axis of the jacket 10.

monitoring wedge pressure). If more tensioning is desired, the surgeon simply pulls more on the free ends 35. If less tensioning is desired, the surgeon can simply bend or stretch the springs 30 against the bias of the springs 30 to cause the opposing coils of the springs 30 to separate slightly a release the drawstrings 32 to release or reduce the degree of tensioning.

From the foregoing detailed description, the invention has been described in a preferred embodiment. Modifications and equivalents of the disclosed concepts are intended to be included within the scope of the appended claims.

released and permit said draw string to be pulled through said coils when said pulling tension is resumed.

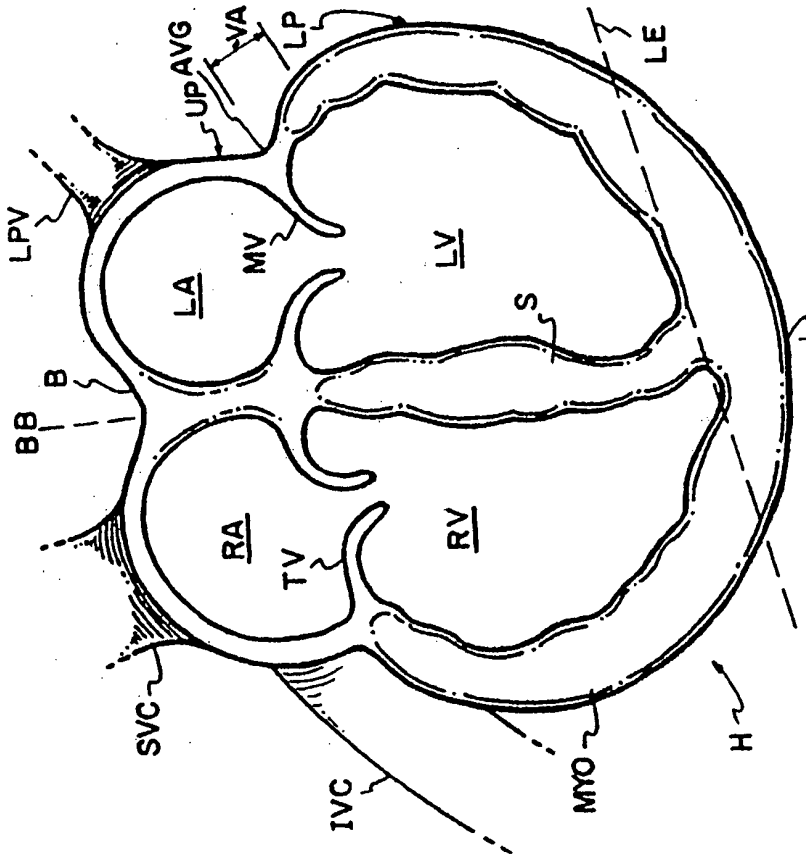

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FIG. 2A

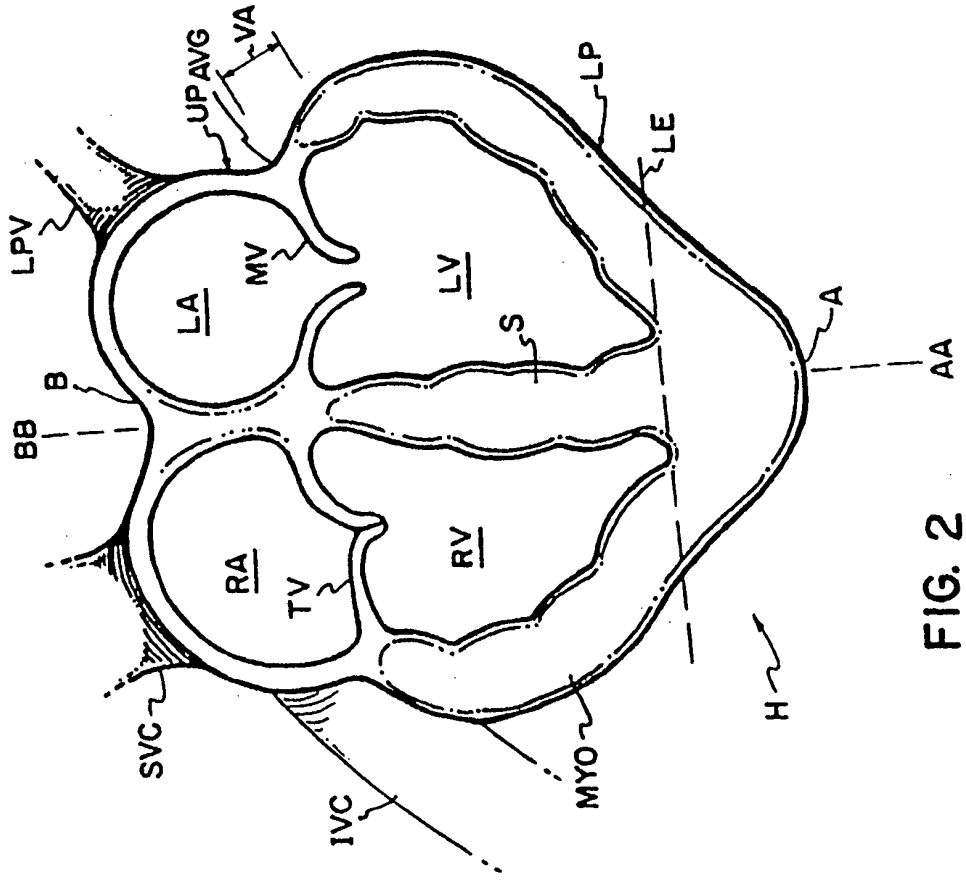
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FIG. 2

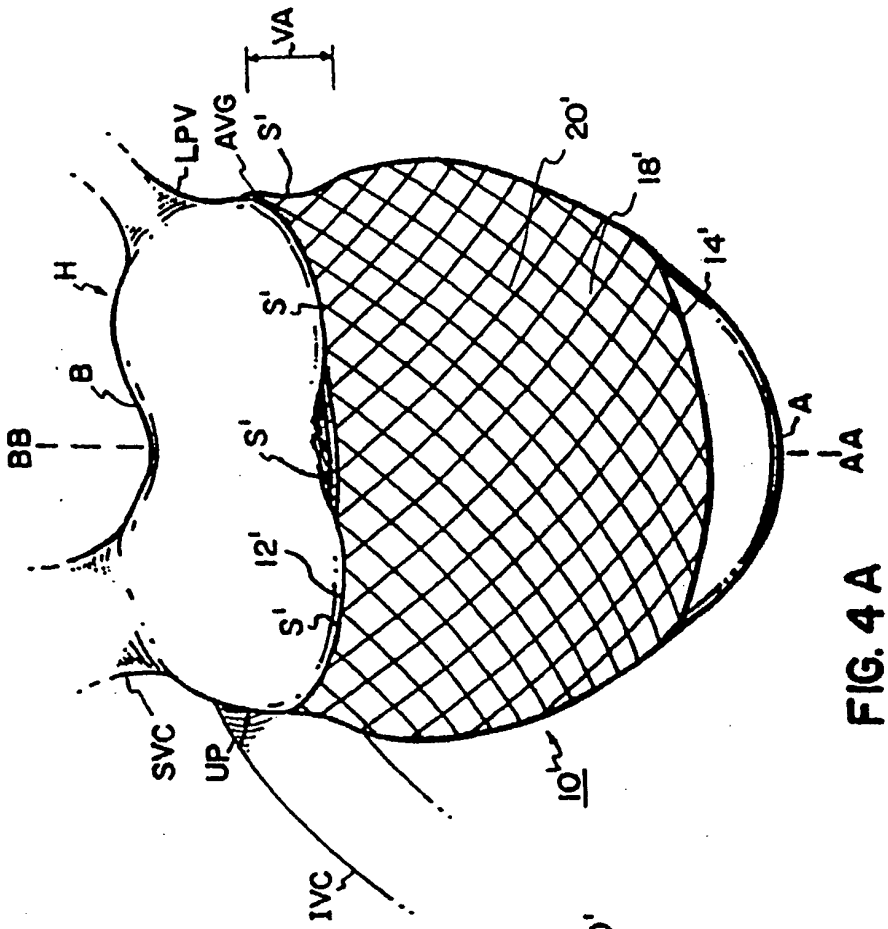

FIG. 4A

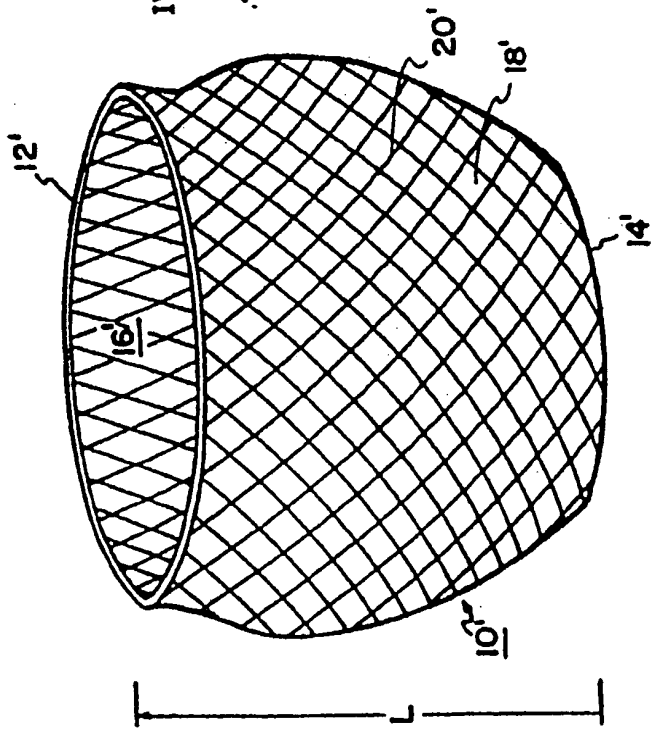

FIG. 4

INTERNATIONAL SEARCH REPORT

Interna ial Application No
PCT/US 00/25809

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/00 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 800 528 A (KUNG ROBERT T V ET AL) 1 September 1998 (1998-09-01) cited in the application column 5, line 34 - line 56; figure 5	1
A	WO 98 58598 A (HAINDL HANS) 30 December 1998 (1998-12-30) cited in the application page 4, line 11 - line 31; figures	1
A	US 5 702 343 A (ALFERNESS CLIFTON A) 30 December 1997 (1997-12-30) cited in the application figures 3,4	1
A	WO 99 44534 A (UNIV CINCINNATI) 10 September 1999 (1999-09-10)	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
21 December 2000	02/01/2001

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